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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,014	09/15/2003	Achim H. Krauss	17619 (AP)	1736

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,014	KRAUSS, ACHIM H.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9-15-03; 5-2-05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10 are pending in the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-10 are rejected on the ground of nonstatutory obviousness – type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 7,070,768 ('768) in view of US 5,290,562 ('562). '768 claims an artificial tanning composition, a method of providing artificial tan to the skin and protecting the skin from the effects of ultraviolet radiation, by administering an effective amount of a compound of formula I, in particular bimatoprost. The compounds encompassed by the patented claims are the same as those claimed in the

instant invention. Instant claims are directed to a method of preventing graying of hair or converting grey hair to the original pigment in hair follicles of a mammal and not a method of providing artificial tan to the skin and protecting the skin from the effects of ultraviolet radiation the patented claims.

'562 teach a method of increasing melanin formation on the skin or scalp by administering a melanin synthesis promoting or a pigmenting compound i.e., a tyrosine or its derivative. '562 teach that increasing the melanin synthesis in the skin damaged by UV radiation can be induced by melanin synthesizing compounds (col.1-2) and that the pigment activity is also increased in the scalp. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the composition containing compound of formula I of '768 for retarding the appearance of grey hair in a mammal in need thereof because '562 teaches that increasing or stimulating melanin synthesis improves the retardation of grey hair together with increasing the melanin pigment. Therefore, a skilled artisan would have expected to inhibit or retard graying of hair or improve the pigmenting with the compound of '768 because of its melanin stimulating activity.

Claim Rejections - 35 USC § 112

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for converting gray hair to the original pigment in the hair follicle of a subject being treated by the instant composition, does not reasonably provide enablement for preventing graying of hair. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Instant claims broadly recite a method of preventing graying of hair, which denotes that administering the instant composition is stopping the process of gray once. Gray hair is caused due o a number of reasons, such as predisposing genetic factors, exposure to UV radiation, natural aging process etc. Further, despite the fact the external or physical causes such UV radiation from sunlight do not always result in gray hair in each and every individual exposed to the radiation. Further, there is no specific time line or age at which graying can occur in different individuals. The instant term "prevention" denotes that the graying process does not occur again during the lifetime of a subject undergoing the instant treatment. A review of the instant specification does not reveal that the experimental data provided includes testing the composition for a period of six months or less, which shows that the gray hair is converted to a dark brown pigment in treated subjects. Thus, the present "prevention" has been shown to be effective for 6 months as opposed to the physiological process of graying of hair which happens over a period years, depending on partial graying or complete graying of hair. Further, applicants have not shown that after 6 months, if the treatment is effective for any length of time i.e., years and that the treatment in successful in completely stopping from gray hairs to appear again. Absent such a data and also in the absence of any description as to the dosage, duration of treatment, age of the subjects etc., one of an ordinary skill in the art would have to perform undue experimentation to practice the claimed prevention of gray hair

because one does not know the required duration of the claimed treatment so as to achieve the "prevention". The instant disclosure enables a skilled artisan in only treating grey hairs with the claimed composition so as to convert the pigment in the hair follicles to original color for about six months period but does not enable a skilled artisan to continue the treatment for ever so as to permanently convert the pigment to original color. For prosecution purposes, instant term "preventing" is construed as "treating".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 1-10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,262,105 to Johnstone.

> Johnstone discloses a method for stimulating the growth of hair comprising administering a composition comprising a prostaglandin or its derivatives to the skin or scalp. Johnstone teaches that the compounds are effective in not only stimulating hair growth but also in increasing the pigmentation of the lashes, which is a result of the melanin production (col. 7, L 15-65). The prostaglandin compounds of Johnstone (col. 9-10) are similar to the instant compounds except for the variable X of the instant claims. Johnstone further teaches lotions, powders, aerosols etc.,

comprising the abov e compounds. While instant claims require X =NR2, where R is a H or an alkyl having 1-6 carbon atoms, Johnstone teaches compounds with ester group on the same position as that of instant X. Johnstone also fails to teach the instant bimatoprost. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ a prostaglandin having an amide or an ester group at the variable X of instant compounds and still use it for converting grey hair to the original pigment in hair follicles or retard graying of hair because a skilled artisan would have understood that the activity or the efficacy of prostaglandin compounds is due their core prostaglandin structure and that the ester or an amide substitution would have minimal effect on the final hair stimulating or pigment producing activity. Hence it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to choose an appropriate derivative of prostaglandin for the claimed effect i.e., preventing grey hair or improve pigment in hair follicles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM - 4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 1615
December 29, 2006

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER